REMARKS

Election/Restrictions

Applicant affirms the election as stated by the examiner in the last office action.

Specification

The specification has been amended as required by the examiner. Additionally, applicant has amended the specification to correct the grammatical error on page 15, line 22 by changing "measuring" to "measured" and the technical error on page 15, line ****.

Claim Rejections - 35 USC § 103

Applicant's undersigned attorney would very much appreciate an interview in the event there are any questions or problems after the examiner has considered the following discussion and the above amendments. The inventor can also be available for an interview.

Applicant's undersigned attorney would like to first point out the features of the invention that distinguish the invention from the prior art. Then the prior art, the initial rejection and the reasons for allowance will be discussed along with the amendment to claim 1.

The Invention

Applicant agrees with most of the observations by the examiner in the last office action and therefore it is apparent that the examiner understands the technology. Consequently, there is believed to be no need for a summary or review.

The principal new contribution of applicant's method is that, when monitoring the ischemic condition for an individual patient, the presence of ischemia for that patient is not diagnosed or recognized as ischemia, unless and until a measured value of mean myocardial electrical impedance exceeds the sum of (1) a computed baseline mean and (2) the computed variance of the series of measurements that were made to obtain the baseline mean. In other words, initial measurements determine a baseline mean impedance and a variance for those baseline measurements. After the baseline is determined, subsequent measurements on the individual patient are periodically made. However, only after a subsequent set of measurements give a computed mean value that exceeds the baseline value by at least the variance is the condition considered to be ischemic. So long as subsequent measurements result in a computed mean that differs from the baseline mean by less than the variance, the patient is not diagnosed as ischemic.

In summary, the prior art does not teach diagnosing the patient as ischemic only after (1) the change in the mean of the periodic measurements of the myocardial electrical impedance, (2) away from the initially computed baseline mean, (3) is more than the variance computed from the initial set of measurements used to compute the baseline. Step (e) of applicant's claim 1 is entirely absent from the prior art.

The Prior Art and Applicant's Invention

Applicant agrees that the examiner is correct in observing that the prior art shows use of the same equipment as used in the performance of applicant's method. Applicant also agrees that the examiner is correct in observing that the prior art shows attaching electrodes to the myocardium and measuring the myocardial electrical impedance. The prior art also shows taking those measurements in a sequence or series of time spaced or periodic measurements. Applicant also agrees that the examiner is correct in observing that the prior art shows plotting and analyzing data from these measurements, although there are important differences in the methods. The prior art also shows that there is a correlation between myocardial electrical impedance and ischemia and that a greater impedance correlates to a greater extent of ischemia.

The examiner is also correct in observing that the Howie article computes and records baseline values for mean myocardial electrical impedance and shows subsequently periodically measuring mean myocardial electrical impedance over an interval of time. However, these measurements were for a study group of subjects, not an individual. It is believed obvious that the use of applicant's method as a diagnostic tool is only applicable and useful when the measurements are taken from one individual. In the prior art, the measurements from the multiple subjects in the group are used to compute a baseline for the group, as well as subsequently measured mean values for the group. The baseline is computed from data from all members of the group. It is a baseline for a group of individuals. Similarly, the standard deviations in the Howie reference are computed from data from the entire group. That gives the standard deviation for data for the entire

group. That standard deviation shows the spread of the data among the multiple individuals in the group which is dependent upon variations among individuals. Such a spread has no meaning or significance when trying to diagnose the condition of the myocardium of an individual.

In order to make this distinction clearer in claim 1, the words "of an individual" have been inserted in claim 1. This is believed not new matter. The facts that applicant's method is for diagnosing an individual, and that the measurements recited in the claims are measurements of one individual, and the same individual, are believed apparent from the specification as a whole and particularly because that is the only way a meaningful diagnosis can be made. Furthermore, the claim as filed already recited, in the singular, "a human myocardium" and thereafter refers to the myocardium. Therefore, it is believed clear that applicant's method is not mixing together the data from all the members of a group but rather is collecting all its data from an individual.

The examiner observed that the Howie reference computes the variance of the myocardial electrical impedance. Applicant respectfully submits that this observation is incorrect. Howie computes the standard deviation, not the variance. The Howie article expressly states, in the first full paragraph that begins on page 15, "Data are reported as mean values with standard deviations." That paragraph does use the word "variance" but that use of variance is in connection with the "comparison between baseline values for each study group" and the ANOVA method, as expressly stated in the same paragraph. Applicant's method has nothing to do with a comparison between baseline values for multiple study groups. Although the ANOVA method itself uses variance, that variance has nothing to do with applicant's invention.

Consequently, Table 1, and the discussion of it, present a baseline that represents mean values computed from a group of measurements of a group of individuals. In other words, the data from the measurements of the multiple individuals of a group is all averaged together to find a mean for the group.

Most importantly, step (e) of applicant's method is entirely absent from, and not obvious from, the prior art. Nothing in the prior art teaches, suggests or gives any reason to perform step (e). Claim 1, step (e), includes "after the mean myocardial electrical impedance changes from the computed baseline value by at least the measured variance". The step (e) wording means that "the extent of change in the myocardial pathophysiologic state" is diagnosed only "after the mean myocardial electrical impedance changes from the computed baseline value by at least the measured variance". In other words, a change in myocardial physiologic state, and in particular ischemia, is indicated only when myocardial electrical impedance rises above a value equal to the baseline value plus the variance computed from the baseline measurements.

The prior art gives no indication as to what amount of increased myocardial electrical impedance constitutes ischemia or any other myocardial physiologic state. The prior art does not say that the amount of change should be at least equal to the variance, or to the standard deviation or to anything else. The prior art is silent on that topic. The prior art does not use either variance or standard deviation for any diagnosis purpose. It merely presents the standard deviation data.

Furthermore, as recited in claim 1, the variance that is used in applicant's method is the variance computed from the baseline measurements. It is not just any variance. The prior art not only computes standard deviation and not variance, but it computes standard

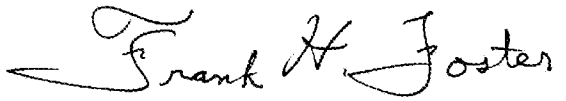
deviation for all measurements. The prior art's use of standard deviation is meaningless with respect to this important aspect of applicant's invention. The standard deviation in the prior art is not used for anything remotely similar to applicant's method.

Consequently, for the above reasons, the claims as amended are believed allowable and reconsideration and allowance are respectfully requested.

The examiner is authorized to communicate with the undersigned attorney by email by the following recommended authorization language: Recognizing that Internet communications are not secure, I hereby authorize the USPTO to communicate with me concerning any subject matter of this application by electronic mail. I understand that a copy of these communications will be made of record in the application file. (authorization pursuant to MPEP 502.03)

The Commissioner is authorized to charge Deposit Account No. 13-3393 for any insufficient fees under 37 CFR §§ 1.16 or 1.17, or credit any overpayment of fees.

Respectfully submitted,



4 June 2008
Date of Signature

Frank H. Foster,
Reg. No. 24,560
KREMBLAS, FOSTER, PHILLIPS & POLLICK
7632 Slate Ridge Blvd.
Reynoldsburg, OH 43068
Voice: 614/575-2100
Fax: 614/575-2149
email: ffoster@ohiopatent.com

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